8. 510(k) Summary

OCT 1 2012

1. Applicant

Shoulder Options, Inc.
100 E. South Main St.
P.O. Box 1458
Waxhaw, NC 28173

Date Prepared: June 5, 2012

Contact Person: John Kapitan, CEO
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2. Device Name

Common/Usual Name: Plate, Fixation, Bone
Classification Name: Single/multiple component metallic bone fixation appliances and accessories
Regulation Number: 888.3030
Product Code: HRS, HWC
Classification: II
Panel: Orthopedic

3. Predicate Devices

The Shoulder Options AFT™ Proximal Humerus Fracture Plate is substantially equivalent to the following devices:

510(k) Number	Device	Manufacturer
K041860	Synthes LCP Proximal Humerus Plate	Synthes
K011815	Synthes LCP Proximal Humerus Plate	Synthes
K963172	Synthes 4.5mm Non-Locking Cannulated Screw	Synthes
K042695	4.5mm NCB Proximal Humerus Non-Locking Screw	Zimmer

4. Description of the Device

The AFT™ Proximal Humerus Fracture Plate is a low-profile, anatomically shaped plate which matches the natural contour of the proximal humerus. The plate is available in 'long' and 'short' configurations with left and right options. The plate contains holes for 3.5mm locking and non-locking screws and 4.5mm partially threaded screws. The screws are available in various lengths. Both the plates and the screws are manufactured from Ti-6Al-4V (ASTM F136). The components are provided non-sterile for single-use.

5. Indications for Use

The AFT™ Proximal Humerus Fracture Plate is intended for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone.

6. Summary of Performance Data

Testing of the AFT™ Proximal Humerus Fracture Plate to demonstrate substantial equivalence included static and dynamic bending testing per ASTM F382-99.

7. Safety & Effectiveness

The AFT™ Proximal Humerus Fracture Plate is substantially equivalent to the Synthes LCP Proximal Humerus Fracture Plate (K041860, K011815), Synthes 4.5mm Non-Locking Cannulated Screw (K963172), and Zimmer NCB Proximal Humerus Non-Locking Screw (K042695). The devices have the same "Indications for Use," are available by prescription only, and are provided non-sterile for single-use only. Based on this and the design similarities, it can be concluded that the AFT™ Proximal Humerus Fracture Plate is both a safe and effective device and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 1 2012

Shoulder Options, Incorporated
% Mr. John Kapitan
CEO
100 East South Main Street
P.O. Box 1458
Waxhaw, North Carolina 28173

Re: K121672
Trade/Device Name: AFT™ Proximal Humerus Fracture Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: August 15, 2012
Received: August 20, 2012

Dear Mr. Kapitan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7. Indications for Use Statement

510(k) Number (if known): K121672

Device Name: AFT™ Proximal Humerus Fracture Plate

Indications for Use:

The AFT™ Proximal Humerus Fracture Plate is intended for fractures and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121672